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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,872

06/11/2007

Sabine Gaisser

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7590

03/30/2010

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B482

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RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

BLAND, LAYLA D

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

03/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/580,872	<b>Applicant(s)</b> GAISSER ET AL.	
	<b>Examiner</b> LAYLA BLAND	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21, 27, 28 and 31-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 27, 28, 31-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/12/2008</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group III, claims 21 and 27-30, in the reply filed on January 14, 2010 is acknowledged. Applicant's amendment filed January 14, 2010, wherein claims 1-20, 22-26, and 29-30 are canceled and claims 32-60 are newly submitted is acknowledged. Applicant's election of species is acknowledged. Upon further consideration, the election of species requirement is withdrawn. Claims 21, 27, 28, and 31-60 are pending and are examined on the merits herein.

This application is a national stage entry of International Application No. PCT/GB04/05001, filed November 29, 2004, which claims priority to United Kingdom Application No. 0327721.7, filed on November 29, 2004. The certified copy of the priority has been filed with the instant Application.

### ***Claim Objections***

Claim 21 is objected to because of the following informalities: the definition of R14 recites  $-C(0)NR^cR^d$ , which should be  $-C(O)NR^cR^d$  (oxygen should be represented by the letter O instead of zero). In the last line of the claim, there are closed parentheses but no open parentheses. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 27, 28, and 31-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said compound is a variant of any of the above which differs in the oxidation state of one or more of the ketide units, wherein said ketide unit is selected from the group consisting of  $\text{-CO-}$ ,  $\text{-CH(OH)-}$ , alkene  $\text{CH-}$ , and  $\text{CH}_2$ ." It is unclear which variations are encompassed by this limitation. A change in oxidation state could include additional atoms and even fragmentation of the molecule. For example, consider the  $\text{CH}_2$  adjacent to nitrogen in the ring in Formula II. A change in oxidation state could change the  $\text{CH}_2$  to a  $\text{CHOH}$ . Further change could result in  $\text{C=O}$ . Further change could result in  $\text{C(O)OH}$  and opening of the ring. Even further change could result in the formation of  $\text{CO}_2$  and fragmentation of the molecule. The claim could be interpreted to encompass this type of modification, and at every position in the molecule where there is  $\text{-CO-}$ ,  $\text{-CH(OH)-}$ , alkene  $\text{CH-}$ , or  $\text{CH}_2$ . It seems unlikely that Applicant intends to claim ring-opened or fragmentation products or those containing additional unspecified atoms. However, the specification does not provide guidance on this point, but only recites the same language as is given in the claim. Thus, it is unclear which changes in oxidation state, and at which positions, are intended.

***Claim Rejections - 35 USC § 102***

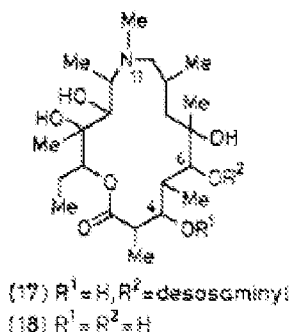
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 27, 28, 31-36, and 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Djokic et al. (J. Chem. Research 1988; (5):152-3).

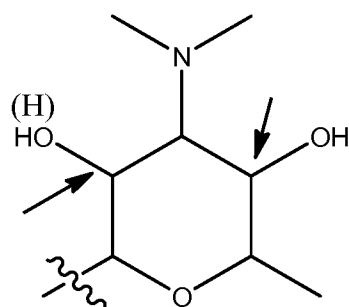
Djokic teaches the following compound [page 152]:



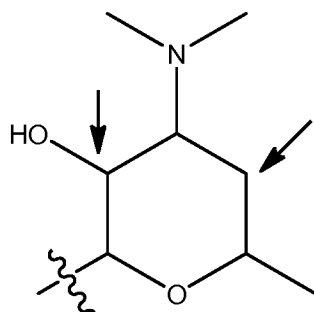
Compound 18 above anticipates the claims when  $R^1$  is ethyl,  $R^2$  is methyl,  $R^3$  is OH,  $R^{14}$  is H,  $R^4$  is methyl,  $R^5$  is methyl,  $R^{13}$  is H,  $R^6$  is methyl,  $R^{15}$  is H,  $R^7$  is methyl,  $R^8$  is H, and  $R^9$  is methyl.

It is noted that claim 28 does not exclude compounds wherein  $R^{15}$  is H or require the alternative sugar structure given for  $R^{15}$ , but only further limits the alternative structure recited for  $R^{15}$ . However, even if claim 28 did require that  $R^{15}$  is the recited sugar, compound 17 shown above anticipates claim 28. The claimed  $R^{15}$  sugar and the corresponding sugar for compound 17 are shown below:

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Claimed



Compound 17

Compound 17 is a variant of the claimed compound which differs in the oxidation state of the  $\text{CH}_2$  or  $\text{CH}(\text{OH})$  units indicated by the arrows. The compounds differ in  $\text{CH}_2$  versus  $\text{CH}(\text{OH})$ , which is a difference in oxidation state. Compounds differing in the oxidation state of  $\text{CH}(\text{OH})$  or  $\text{CH}_2$  are encompassed by the claims.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Examiner, Art Unit 1623